

# **EXHIBIT B**

## **Inspections, Compliance, Enforcement, and Criminal Investigations**

### **Hirzel Canning Company 29-Aug-01**

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Cincinnati District Office  
Central Region  
6751 Steger Drive  
Cincinnati, OH 45237-3097  
Telephone: (513) 679-2700  
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August 29, 2001  
WARNING LETTER  
CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Karl A. Hirzel, President  
Hirzel Canning Company  
411 Lemoyne Road  
Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of your firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of the Federal Food Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

**Dei Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)**

The above product is misbranded within the meaning of Section 403 (a)(1) of the Act in that its labeling is false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is "fresh," when in fact it has been thermally processed. The Food and Drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

**Dei Fratelli Fresh & Ready CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei Fratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)**

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labeling is false or misleading. The statements "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact they have been thermally processed. In addition, according to the ingredient statements, the products contain at least two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli® \*\*\*. CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)(1)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based on the information on the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other things, the product contains no more than 360 mg of sodium.



Furthermore, the Dei Fratelli ® \*\*\* CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(1)(A) of the Act because the labels bear nutrient content claims that are not authorized by regulation for the Act or are not consistent with an authorizing regulation. The claims include "\*\*\* a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source" is considered to be an unauthorized synonym for "high." FDA has defined the nutrient content claim "high" in 21 CFR 101.54(b). "High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "\*\*\* great source of \*\*\* Lycopene" is not authorized. In addition, the Dei Fratelli ® \*\*\* CONCENTRATE/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as part of the common or usual name of an ingredient. Ingredients must be declared by their common or usual name, as stated in section 403(i)(2) of the Act and 21 CFR 101.4(a)(1). Optional information, such as the term "fresh" is not permitted.

Also, the Dei Fratelli ® \*\*\* CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA's policy regarding the use "natural," means that nothing artificial or synthetic has been included in, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen(15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,  
Henry Fielden  
District Director  
Cincinnati District

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